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201-15897

May 9, 2005

The Honorable Stephen L. Johnson, Acting Administrator U.S. Environmental Protection Agency P.O. Box 1473
Merrifield, VA 22116

ATTN: Chemical Right-to-Know Program
Dechlorane Plus® (CAS# 13560-89-9)

Dear Mr. Johnson:

Occidental Chemical Corporation ("OxyChem") has carefully considered comments from Environmental Defense ("ED") on the test plan and robust summary for Dechlorane Plus® (CAS# 13560-89-9; Dech Plus). This letter summarizes our conclusions regarding the five ED comments:

Comment 1: Study Quality

ED stated that many of the studies were "...old, poorly designed and/or were not conducted under GLP and...not sufficient to address the requirements of the HPV Challenge...". OxyChem believes the studies are sufficient and should not be repeated.

The studies outlined in the HPV submission were appropriately designed to provide useful toxicological information for Dech Plus, and the study designs are considered to be consistent with good scientific practices. Many of the studies were conducted prior to implementation of GLPs, but the data generated from these studies are scientifically valid and useful in assessing the potential hazards and risks arising from Dech Plus. The purpose of the HPV Challenge initiative was to place into the public domain basic hazard information for chemicals, regardless of when the studies were conducted or whether the studies were conducted by GLPs. The robust summary and test plan submitted by OxyChem certainly meets the principles and goals of the HPV Challenge. Repetition of these studies would result in unnecessary use of test animals and laboratory resources.

Comment 2: Information on Production, Transport and Use

OxyChem agrees that information on production, transport and use is critical to an assessment of product risk. Indeed, careful consideration of this information forms the basis of our safe handling and transport recommendations. Because of our recommendations, OxyChem believes that there is very little, if any, human or environmental exposures to Dech Plus.

Dech Plus is manufactured solely for industrial customers. After manufacture, Dech Plus is shipped to our customers where the material is entrapped and immobilized into a polymer matrix thereby minimizing human and environmental exposures. The product is shipped to our customers in 50 pound bags that are palletized. Each pallet is also shrink wrapped to prevent movement or damage during shipment.

Prior to incorporating the material into a polymer matrix, the potential for exposure to Dech Plus is very low. Dech Plus is a white powder that is stable to 300 °C, has very limited solubility in water, and is not volatile. These properties enable facilities to easily control exposures to Dech Plus using conventional engineering controls and good hygiene practices.

Dech Plus is a flame retardant, and our customers use it in two primary applications in polymers - nylon that incorporates Dech Plus into electrical connectors and polyolefins that incorporates Dech Plus into commercial wire and cable. The addition of Dech Plus gives these polymers enhanced flame retardant properties that increase the safety of the products.

The potential for exposure to Dech Plus from these products is remote as the material is immobile. In addition, polymers incorporating Dech Plus are used in products that are not handled by, for example, children.

## Comment 3: Chemical Similarity

OxyChem believes the Dech Plus molecule does not pose a risk to the environment. The exposure potential associated with the industrial use of Dech Plus is not similar to those exposures that occurred with prohibited pesticides, e.g., mirex. Furthermore, the molecular structure of Dech Plus does not contain a biologically reactive site as do the prohibited pesticides. For example, the aldrin molecule consists of a double bond that is the reactive site of the molecule. Metabolism of aldrin to a reactive epoxide at this double bond is responsible for the toxicity of aldrin. In contrast, Dech Plus does not appear to be metabolized to a reactive intermediate.

Dech Plus and the prohibited insecticides do have a common starting material, hexachlorocyclopentadiene, and are made using a Diels-Alder reaction. However, Dech Plus is reacted with cyclooctadiene to produce a much larger molecular weight compound. A molecular model of Dech Plus looks like a big ball of chlorine molecules, and this structure prevents it from reacting with any materials. This stable structure is the reason Dech Plus is an excellent flame retardant.

ED's comments imply that Dech Plus could cause effects in the environment that are similar to the effects caused by the prohibited insecticides. The insecticides were applied on the soil, while Dech Plus is not. Dech Plus is used as a flame retardant, not as an insecticide. As discussed above, Dech Plus is trapped within polymer matrices and cannot be released to the environment.

## Comment 4: Bioaccumulation Potential

The ED stated that the studies that assed the bioaccumulation potential of Dech Plus were inadequate. The ED believes that longer exposures to lower doses should have been assessed. OxyChem disagrees.

Six different aquatic toxicity studies were conducted with Dech Plus or with a mixture of dechloranes that included Dech Plus, and some of these studies were conducted over a 30-day exposure period. In some studies, Dech Plus was added to the aquatic environment directly but in others, Dech Plus was first dissolved in acetone prior to adding to the aquatic environment. Regardless of the way in which Dech Plus was added to the aquatic environment, dose levels of up to 100 ppm were achieved, and these dose levels are considered to represent worst-case concentrations in the aquatic environment. No toxicity was observed in these studies with Dech Plus, and any toxicity that was observed was considered due to acetone.

These studies further demonstrated that Dech Plus will agglomerate in water solutions because of its hydrophobic characteristic, thereby reducing the potential for significant systemic availability and limiting the potential for chronic toxicity. Finally, because of the water insolubility of Dech

Plus and the resulting agglomeration that occurs in water, containment and remediation of Dech Plus is easily accomplished in the unlikely event of any accidental release.

Dech Plus will potentially bioaccumulate, although the experimental evidence demonstrates that a steady state tissue concentration in fish is reached by seven days, i.e., longer exposures do not significantly result in increased tissue concentrations. Because Dech Plus may be metabolized (see below), compared with other highly chlorinated pesticides, e.g., mirex, elimination of Dech Plus will occur more readily. Therefore, these other chlorinated pesticides will have longer tissue residence times. Hence, chronic toxicity from bioaccumulation associated with Dech Plus is considered to be less of an environmental concern than that associated with mirex, kepone and other chlorinated, lower molecular weight pesticides.

## Comment 5: Metabolism Studies

Although two metabolism studies have been conducted with Dech Plus, the study conducted by Saunders and Quistad (Reference 20 of the HPV Submission) is the more comprehensive study. In this investigation, rats were administered a single oral dose of <sup>14</sup>C-Dech Plus at a dose of 1 or 113 mg/kg. In addition, rats were administered unlabeled Dech Plus in the diet for 14 days at a dietary concentration of 1%. After 14 days of treatment, the rats were administered <sup>14</sup>C-Dech Plus at 1 mg/kg. Blood, urine and feces were collected periodically, and tissue levels determined at 4 days.

As shown in the following table, greater than 90% of the administered dose was recovered during this study with elimination in the feces accounting for the majority of the recovered material.

Table 1: Mass Balance of <sup>14</sup>C 4 days following treatment with Dech Plus<sup>1</sup>

Percent of Administered Dose				
Sex	Female	Male	Female	Female
Dose (mg/kg)	1.1	0.98	113	1% in Diet/ 0.89 <sup>2</sup>
Urine	0.07	0.01	0.009	0.03
Feces	83.5	92.7	96.5	102
Carcass	7.9	8.5	1	6.9
Total Recovery	91.4	101	97.5	109

- 1. Average of 2 rats/group
- 2. Rats fed for 14 days with diets containing 1% unlabeled Dech Plus then given a single oral dose of label Dech Plus

As can be seen by the above table, increasing the oral dose decreased the amount of absorbed compound as measured by residual levels in the carcass and excretion through the urine. Hence, gastrointestinal absorption is dose limiting. These data clearly indicate that, in spite of the limited potential for Dech Plus to bioaccumulate, the compound is not well absorbed. Indeed, a majority of the compound is eliminated through the feces.

At the end of the 4-day study, selected tissues were collected and residual levels of <sup>14</sup>C determined for each group. For those rats treated with a single oral dose of Dech Plus, the liver contained the highest residual levels (1.6-2.29% of the administered dose) with the ovaries, lungs and kidney representing, in total, about 1% of the administered dose. The stomach and intestinal tract contained approximately 0.4% residual Dech Plus. All other tissues examined, including abdominal and pericardial fat, contained less than 0.1% residual Dech Plus with the carcass containing about 5% residual Dech Plus. The residual levels observed in rats treated with a single oral dose of Dech Plus were comparable to those rats fed Dech Plus in the diets followed by oral administration of labeled Dech Plus. Taken together, these data indicate that Dech Plus is not well absorbed from the gastrointestinal tract thereby accounting for the high levels excreted through the feces.

In plasma, peak radioactivity levels were reached within about 10 hrs following oral administration of 1 mg/kg Dech Plus, but these levels declined by about 50% at 48 hrs post-administration. At peak levels, approximately 65% of the label was found to be parent compound with the remainder considered a polar metabolite(s), although this metabolite was not identified.

Overall, these data demonstrate that Dech Plus is not well absorbed in spite of its high partition coefficient. Furthermore, the compound is eliminated primarily through the feces as the parent compound although there is evidence suggesting that at least one metabolite may be formed. In addition, Dech Plus does not appear to accumulate in fat, in contrast to many other highly chlorinated pesticides, e.g., mirex, and residual levels that are found occur in tissues that are highly vascular such as the liver and kidneys. Thus, the compound would be eliminated further over time rather than accumulating into fat.

OxyChem is committed to the American Chemistry Council Responsible Care® program and to product stewardship. OxyChem is also committed to fulfilling its obligation under the High Production Volume (HPV) Challenge Program. However, OxyChem also believes that testing should be performed only when the testing is justified. Because Dech Plus is used in a controlled manner and that human and environmental exposures are very limited, additional testing as suggested by ED is not warranted. Therefore, OxyChem respectfully considers the commitment for Dech Plus under the HPV Challenge Program to be complete.

Please contact Debbie Schober by phone at (972) 404-4969 if you have any questions regarding this matter.

Sincerely,

Stephen B. Kemp Vice President Health, Environment, Safety, & Security